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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/664,213
Filing Date: September 16, 2003
Appellant(s): MOSTAFAVI ET AL.

BLAKELY, SOKOLOFF, TAYLOR, & ZAFMAN
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 2/23/11 appealing from the Office action mailed 7/13/10.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 1, 3, 5-16, 49, 51-58, 62-79, and 81-89 are rejected.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the

subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

2002/0193685	MATE ET AL.	12-2002
2002/0065461	COSMAN	5-2002
2003/0007601	JAFFRAY ET AL.	1-2003
5757953	JANG	5-1998
5446548	GERIG ET AL.	8-1995
6073044	FITZPATRICK ET AL.	6-2000
5622187	CAROL	4-1997
6398710	ISHIKAWA ET AL.	6-2002

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

Claims 1, 3, 5-7, 13-14, 16, 49, 51-58, 62, 76-77, 82-84, and 87-89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mate et al. (US 2002/0193685) in view of Cosman (US 2002/0065461) and Jaffray et al. (US 2003/0007601).

Mate et al. show a guided radiation therapy system. The radiation delivery source can be a linear accelerator, or any other type of radiation therapy device ([0034]). The radiation device has a machine isocenter associated with it. This is the isocenter of the radiation beam ([0035]). A plurality of markers are positioned in the target to mark the actual location of the target in the body. These markers define a target isocenter. The target isocenter is selected as part of a treatment planning procedure by a treatment planning system ([0054]). The position and orientation of each marker is obtained using a radiofrequency signal and used to determine the precise location of the target isocenter ([0036]-[0037]). The markers can be implanted in the patient, and delivered by an applicator needle ([0041]). The actual position of the target isocenter is compared to the position of the machine isocenter, and if they are spatially misaligned, the target can be moved relative to the machine isocenter. Once the target isocenter and machine isocenter are coincident, the radiation treatment is applied ([0039]). Determining the position manually would be a well known and obvious modification to one of ordinary skill in the art. Mate et al. fail to show using more than one imaging modality.

Cosman discloses a surgical positioning system. Cosman teaches that X-ray imaging can be used to further refine the positioning of the isocenter. The X-ray images can be used to determine the position of markers within the body. The use of X-ray imaging further improves the accuracy of the alignment ([0064]-[0069]). Furthermore, the same imaging modality could be used. Cosman teaches the use of preoperative CT scanning ([0064]) and the use of interoperative CT scanning as well ([0065]). These

imaging systems are located on different machines, one being used for planning the treatment and one being used for the actual treatment. As indicated by appellant's specification ([0064]), various configurations are known in the art and may be used, including imagers located on a gantry or as part of a treatment table. Cosman also teaches that both the treatment machine and the patient can be moved to accomplish desired positional relationships ([0024]). The treatment machine is rotatable ([0025]). A multileaf collimator or any other type of known collimator can be used as well ([0026]). The angle and shape of the treatment beam can be controlled ([0043]).

Jaffray et al. disclose a radiation therapy system. Jaffray et al. teach that kV or MV imaging can be used to aid in lesion location ([0008]).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have used a second imaging system to align the patient and the treatment beam as taught by Cosman in the system of Mate et al. The use of a second imaging system will increase the accuracy of the alignment. Furthermore as part of the combination of using a second imaging system to aid in patient alignment as taught by Cosman, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have modified the system of Mate et al. to locate the position of the markers using imaging rather than a radiofrequency signal as taught by Cosman. Mate et al. recognize that there are a variety of known techniques for locating the position of a target within the body which could be employed ([0074[).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the combined device of Mate et al. and Cosman

with any imaging modality which will aid in the radiation therapy process, kV or MV imaging being two such possible imaging modalities which are known for aiding in lesion location.

Claims 8-9, 12, 78-79, and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mate et al. (US 2002/0193685) in view of Cosman (US 2002/0065461) and Jaffray et al. (US 2003/0007601) as applied to claims 6 and 7 above, and further in view of Jang (US 5757953).

Jang discloses an automated method and system of region decomposition in digital radiographic images. Jang teaches that shape filtering and connected component analysis are used to decompose an image into meaningful subregions (column 11, lines 30-67). The median filters can be used to smooth the image (column 9, line 3). The details of the operation of median filtering are old and well-known in the art.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have used a median filter and connected component analysis as taught by Jang, in the combined system of Mate et al., Cosman, and Jaffray et al.. One of ordinary skill in the art would have used these techniques to divide the image into useful regions, and to find the location of the markers in the images. In addition, by determining the location of markers in the image, the user would know which objects are not markers. It would be obvious to one of ordinary skill in the art to make sure that

these objects would then not be considered as markers, and would not be used for any further steps, such as during the alignment.

Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mate et al. (US 2002/0193685) in view of Cosman (US 2002/0065461) and Jaffray et al. (US 2003/0007601) and Jang (US 5757953) as applied to claim 8 above, and further in view of Gerig et al. (US 5446548).

Gerig et al. disclose a patient positioning and monitoring system. Gerig et al. teach the use of an epipolar line constraint (column 5, lines 19-43). Such a technique is old and well known in the art.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have used an epipolar line constraint technique as taught by Gerig et al. in the combined system of Mate et al., Cosman, Jaffray et al., and Jang. One of ordinary skill in the art would use such a technique to aid in aligning the markers in the sets of images.

Claims 15, 63-72, and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mate et al. (US 2002/0193685) in view of Cosman (US 2002/0065461) and Jaffray et al. (US 2003/0007601) as applied to claims 1 and 14 above, and further in view of Fitzpatrick et al. (US 6073044).

Fitzpatrick et al. disclose a method for determining the location in physical space of a point of a fiducial marker. Fitzpatrick et al. teach that a rigid body transform is

necessary to register and align the coordinate systems of two imaging modalities (column 1, lines 42-58). A rigid body transform technique is old and well known in the art.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have used a rigid body transform technique as taught by Fitzpatrick et al., in the combined system of Mate et al., Cosman, and Jaffray et al. When using two imaging modalities, such a technique will allow for the two imaging spaces to be properly registered and aligned, and thus the markers in the two images to be aligned. This will allow for the proper positioning adjustment to be determined and executed.

Also, it would have been obvious to have used the same angle for image as for a treatment beam, as this will reduce the amount of time between acquiring images and moving the treatment system into the proper location, because it is already in the proper location. A shorter time between imaging and treatment will prevent more motion from occurring in between, which would reduce the accuracy of the system.

Claims 73 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mate et al. (US 2002/0193685) in view of Cosman (US 2002/0065461) and Jaffray et al. (US 2003/0007601) and Fitzpatrick et al. (US 6073044) as applied to claim 64 above, and further in view of Carol (US 5622187).

Carol discloses a method and apparatus for patient positioning for radiation therapy. Carol teaches that multiple positioning images can be acquired and a triangulation technique used (column 8, line 61-column 9, line 25).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have acquired images from different angles as taught by Carol in the combined system of Mate et al., Cosman, and Jaffray et al. Acquiring an image from more than one angle provides additional data that can be used for three-dimensional reconstruction. If the images were acquired at the same angle, this would not be possible.

Claims 85-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mate et al. (US 2002/0193685) in view of Cosman (US 2002/0065461) and Jaffray et al. (US 2003/0007601) as applied to claims 1 and 58 above, and further in view of Ishikawa et al. (US 6398710).

Ishikawa et al. disclose a radiation dosimetry system. Ishikawa et al. teach the use of implantable devices which measure the radiation delivered to the target site (column 4, lines 25-50).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have modified the combined system of Mate et al., Cosman, and Jaffray et al. to measure the radiation dosage at the target site as taught by Ishikawa et al. Such techniques are well known in the art, and are commonly used in

radiation treatment systems, as they allow the physician to determine the optimal radiation dose to treat the patient with, without damaging nearby healthy tissue.

(10) Response to Argument

First, the examiner would like to address a misconception present throughout appellant's arguments. Appellant argues that the Cosman reference relies upon external, camera imaged markers. However, these markers are **not** relied upon by the examiner, as the examiner has made clear in prior arguments. The examiner has cited paragraphs [0064]-[0069] in Cosman. In [0064] Cosman refers to initial scanning by a CT system with fiducial markers. In paragraph [0067] Cosman refers to further refining the internal target position to an isocenter by using X-ray images from an x-ray machine or portal imager (a common device on modern LINACS), to visualize radiopaque markers implanted in tissue. This step does not refer to external, camera imaged markers, but rather to implanted markers imaged via x-ray. Thus, appellant's arguments in regards to the external, camera imaged markers of Cosman found throughout the bulk of appellant's arguments are moot, as they are not relied upon in the rejection. Furthermore while also moot, appellant states that Mate teaches against using external markers. This is simply false as Mate devotes entire sections of the disclosure to an alternative embodiment which employs surface mounted markers, such as in paragraph [0064].

Next the examiner believes it would be most beneficial to respond to appellant's arguments by describing an overall view of the combination of Mate et al. and Cosman.

Mate et al. essentially teaches the main concept of appellant's invention, which is using markers to align a patient for a radiation treatment. Mate et al. however locate the markers by using markers which emit a radiofrequency which can then be detected externally. Appellant's invention on the other hand, uses imaging to locate the markers. However, Mate et al. note in paragraph [0074] that "In general, in the following claims, the terms used should not be construed to limit the invention to the specific embodiments disclosed in the specification and the claims, but should be construed to **include all target locating and monitoring systems that operate in accordance with the claims to provide apparatus and methods for locating, monitoring, and/or tracking the position of a selected target within a body."** Thus, Mate et al. is clearly aware of other apparatus and methods for locating the markers within the body. The examiner thus combines the Cosman reference, which describes a similar patient alignment system but using imaging to locate markers rather than (substituting) detection of an RF signal. In addition, Mate et al. also image markers, although for tracking the position of a tumor within the body ([0060]-[0063]). For these reasons the examiner feels that the combination of the references is appropriate, and it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the system of Mate et al. by adding onto or substituting the x-ray imaging marker locating technique of Cosman. Cosman provides the motivation for doing so, as stated in [0067], "Further refinement of internal target positioning to an isocenter can be achieved by x-ray imaging". Thus, one of ordinary skill in the art would seek to improve the accuracy of the Mate et al. system through "further refinement" by the x-ray imaging

technique taught by Cosman, and such a combination does not require the use of optical imaging techniques.

It should also be noted that appellant's claims do not necessarily require that the determination of the coordinates is performed using the images. Thus the markers detected by an RF signal in Mate et al. would be sufficient to meet those limitations of the independent claims. In any case, as described above, it would be obvious to modify Mate et al. in view of Cosman to obtain the location of markers via imaging.

In regards to appellant's arguments regarding kV and MV imaging, this limitation is taught by a third reference Jaffray et al., which teaches a similar radiation therapy system which employs these imaging modalities. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the combined device of Mate et al. and Cosman with any imaging modality, such as those taught by Jaffray et al., which will aid in the radiation therapy process, kV or MV imaging being two such possible imaging modalities which are known for aiding in lesion location.

In regards to appellant's arguments regarding the dependent claims, such as 62, appellant has attacked the references individually, and does not consider the combination of references. The combination of Mate et al. and Cosman would result in Mate et al. using imaging to locate markers rather than an RF signal, and would thus use the location obtained by imaging to perform a variety of other features such as patient alignment.

Furthermore, appellant also states in these sections, such as in regards to claim 82, that "Cosman only teaches that diagnostic X-rays or high energy X-rays can be used to visualize markers prior to treatment (see paragraph 67)." The examiner believes that appellant has misconstrued what Cosman means. The quote from Cosman paragraph [0067] is "Thus, diagnostic x-rays from machines 80 and 81 or high energy X-rays for portal imaging can be used to visualize internal anatomy such as bones **and/or radiopaque index markers placed on the skin or implanted in bones or tissue within the patient prior to treatment**" (emphasis added). Thus, it can be seen that Cosman refers to the implantation of the markers prior to treatment, not imaging prior to treatment. Indeed, appellant's interpretation would not make sense in the context of the paragraph which refers to further refinement of the target positioning by imaging. Furthermore by referring to "radiopaque" markers, it is clear that these are not optical markers which need to extend out of the body to be properly imaged by an optical system/camera. The term radiopaque is used to refer to markers which are detected by an x-ray system (not a camera), and can be implanted completely within the patient while still showing up properly on the x-ray image.

In regards to appellant's arguments regarding the dependent claims, such as 88, appellant has attacked the references individually, and does not consider the combination of references. The combination of Mate et al. and Cosman would result in Mate et al. using imaging to locate markers rather than an RF signal, and would thus use the location obtained by imaging to perform a variety of other features such as using an imaging system during the treatment time to align the patient.

In regards to appellant's arguments regarding claims 63 and 64, as stated above ([0060]-[0063]), Mate et al. do show that the markers can be imaged over time to determine if they have moved in regards to a tumor, and that the radiation treatment plan can be adjusted in view of any movement (change of spacing).

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Jonathan G Cwern/

Examiner, Art Unit 3737

Conferees:

/Ruth S. Smith/

Primary Examiner, Art Unit 3737

/Sue Lao/

Primary Examiner